REMARKS

This Response is submitted in reply to the non-final Office Action mailed on October 16, 2008. The Office Action provided a three-month shortened statutory period in which to respond, ending on January 16, 2009. Accordingly, this Response is timely submitted. No fees are believed due with this Response. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-731 on the account statement.

Claims 1-11 are pending in this application. Claims 6-11 were previously withdrawn. In the Office Action, Claims 1-5 are rejected under 35 U.S.C. §103. Applicants do not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicants reserve the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application. Applicants respectfully traverse the rejections and submit that the rejections should be withdrawn.

In the Office Action, Claims 1-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. 6,194,379 to McEwen et al. ("*McEwen*") in view of U.S. Patent No. 5,714,472 to Gray et al. ("*Gray*"). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Independent Claim 1 recites, in part, a nutritional composition for promoting wound healing comprising not more than 1.8% of the total calories of the composition as arginine and at least 3% of the total calories of the composition being proline. In recent years, much attention has focused on the role of arginine in wound healing. An adequate supply of arginine is clearly relevant to the wound healing process. However, arginine is also a precursor for the formulation of nitric oxide which acts as a vasodilator and enhances growth hormone secretion. It is not desirable for critically ill individuals to be exposed to high amounts of nitric oxide and yet this will inevitably happen if such individuals receive nutritional supplements containing high levels of arginine. Moreover, it is quite likely that a high proportion of elderly, bedridden or critically ill patients at risk of developing pressure sores will also suffer from conditions for which high levels of nitric oxide are contra-indicated. See, specification, page 2, lines 8-17. Accordingly, the present invention is supplemented with proline in a quantity sufficient to facilitate collagen synthesis and small amounts of arginine that account for no more than 1.8% of the total calories

of the compositions. See, specification, page 3, lines 9-32. In contrast, Applicants respectfully submit that the cited references fail to disclose each and every element of the present claims. Further, Applicants also submit that the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

McEwen and *Gray* fail to disclose or suggest each and element of the present claims. Specifically, *McEwen* and *Gray* fail to disclose or suggest a nutritional composition comprising at least 3% of the total calories of the composition being proline as required, in part, by the present claims. Instead, *McEwen* is entirely directed toward an elemental liquid nuttitional product useful for providing nutrition to a patient having a malabsorption condition by enterally feeding to the patient a nutritional composition having a specific caloric density. See, *McEwen*, Abstract. Indeed, *McEwen* fails to even disclose the use of proline in a nutritional composition at any place in the disclosure, let alone at least 3% of the total calories of the composition being proline.

Similarly, *Gray* is entirely directed toward a composition including at least 3% of the total calories of arginine and discloses less than 2% of proline. See, *Gray*, col. 4, lines 57-67. The Patent Office asserts that *Gray* teaches a composition containing "proline at a caloric percentage of between 4 and 6%." See, Office Action, page 2, lines 24-25. However, the portion of *Gray* cited by the Patent Office clearly discloses that "approximately 25% of the total caloric content of the product is protein" and that "approximately 80% to 85% of the protein will be partially hydrolyzed casein, approximately 13% to 15% arginine and approximately 4% to 6% proline." See, *Gray*, col. 4, lines 57-67. Since the composition of *Gray* contains 4% to 6% proline of the 25% of the total caloric content of protein, the composition of *Gray* contains only 1% to 1.5% of the total caloric content of proline. As such, Gray cannot disclose or suggest a nutritional composition comprising at least 3% of the total calories of the composition being proline as required, in part, by the present claims.

Further, Applicants also respectfully submit that the skilled artisan would have no reason to combine the cited references to arrive at the present claims because *Gray* teaches away from the combination with *McEwen* and from the present claims. For example, the formulations of *Gray* are explicitly disclosed as including "at least 3% of the total calories as arginine." *Gray* further discloses that "[e]nhanced wound healing with arginine is believed to be provided at quantities greater than 3% of the total calories." See, *Gray*, col. 6, lines 58-62. As discussed

above, this is in direct contrast to the present claims, which require, in part, a nutritional composition for promoting wound healing comprising not more than 1.8% of the total calories of the composition as arginine. As is also discussed above, arginine is a precursor for the formulation of nitric oxide which acts as a vasodilator and enhances growth hormone secretion. It is not desirable for critically ill individuals to be exposed to high amounts of nitric oxide and yet this will inevitably happen if such individuals receive nutritional supplements containing high levels of arginine. It is also quite likely that a high proportion of elderly, bedridden or critically ill patients at risk of developing pressure sores will also suffer from conditions for which high levels of nitric oxide are contra-indicated. See, specification, page 2, lines 8-17. Accordingly, the present invention is supplemented with small amounts of arginine that account for not more than 1.8% of the total calories of the compositions. See, specification, page 3, lines 9-32.

Gray also teaches away from a combination with *McEwen* since *Gray* explicitly discloses "at least 3% of the total calories as arginine" and *McEwen* discloses compositions comprising about 1% arginine with respect to the total calories of the nutritional products. See, *McEwen*, col. 9, lines 3-5. As such, because the cited references disclose completely different amounts of arginine, the skilled artisan would have no reason to combine *Gray* with *McEwen* to arrive at the present claims. In fact, what the Patent Office has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Instead, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Applicants respectfully submit that such a reason is not present in the instant case.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Patent Office is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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